IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1644

Application of:	Rittershaus & Thomas
Serial No.:	09/943,334
Filed:	August 30, 2001
Entitled:	MODULATION OF CHOLESTERYL ESTER TRANSFER PROTEIN (CETP) ACTIVITY

Examiner: 1644

Art Unit: M. Belyavskyi

Attorney Docket No.: TCS-411.1P US-1

Commissioner for Patents
Washington, D.C. 20231

TRANSMITTAL LETTER

Sir:

Transmitted herewith: [X] a Response to Office Action Under 37 CFR § 1.141 and 35 USC § 121 (Species Election); [X] a return receipt postcard, to be filed in the above-identified patent application.

PAYMENT OF ADDITIONAL FEES

[ ] A check in the amount of $_____ in payment of the fees is transmitted herewith. {check no. }

[X] The Commissioner is hereby authorized to charge payment of any additional fees required in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to Deposit Account No. 50-0268. A duplicate of this transmittal letter is submitted herewith.

Respectfully submitted,

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Stephanie L. Leicht
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Election #5
5/14/02

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Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO OFFICE ACTION UNDER 37 CFR § 1.141 AND 35 USC § 121 (SPECIES ELECTION)

Sir:

This paper is made in response to an Office Action (Paper No. 4), dated April 8, 2002, in the above-identified divisional application in which the Examiner required Applicants to elect a species as the basis for examining pending Claims 28, 29, and 37-39.

As this paper is being filed one month from the date of mailing of the Office Action, no fee is believed to be required. However, to avoid abandonment, the Commissioner is hereby authorized to charge payment of any fee required in connection with this paper to Deposit Account No. 50-0268.

REMARKS

In the Office Action, the Examiner noted the entry of Applicants' Preliminary Amendment of April 30, 2001. Thus, Claims 28, 29, and 37-39 are pending in this application.

The Examiner also noted in the Office Action that this application is in compliance with the regulations for patent applications containing a sequence listing.

In addition to the above, the Examiner stated that Applicants are required to elect a species from Claim 29 as the basis for prosecuting the pending claims. For the reasons given below, Applicants respectfully traverse the species election requirement.

The Examiner's reason for requiring an election of species was as follows:

> "This application contains claims directed to the following patentably distinct species of the claimed Invention of a method for therapeutically or prophylactically treating arteriosclerosis wherein *the antigenic peptide are [sic] selected from the group recited in the claim 29*.
>
> "These species are distinct because their structure, physicochemical properties and mode of action are different and a person of ordinary skill in the art would not envision one in view of the other.
>
> "The examination of species would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.
>
> "Applicant is required under 35 U.S.C. § 1.121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable."

(paragraph 4, p. 2 of the Office Action, emphasis added).

First, Applicants note that the Examiner's statement in the first paragraph of the above quote from the Office Action is not an accurate characterization of Applicants' claimed invention. Applicants' claimed method of treating atherosclerosis uses an antigenic vaccine peptide, which peptide comprises *two distinct portions* that are linked together, i.e., a portion that contains a helper T cell epitope and another portion that contains a B cell epitope of the protein, cholesteryl ester transfer protein (CETP). Thus, contrary to the Examiner's statement above, an antigenic peptide used in Applicants' claimed method is *not* merely a helper T cell epitope such as one of the examples listed in Claim 29.

In addition, the Examiner's statement in the above quote from the Office Action is also inaccurate because it implies that the list of several examples of helper T cell epitopes in Claim 29 is the limit of the scope of the disclosure with respect to this component. However, Applicants' claimed method is not limited only to the use of peptides including a helper T cell epitope selected only from the few examples of helper T cell epitopes listed in Claim 29.

An example of an antigenic vaccine peptide useful in Applicants' claimed method of treating atherosclerosis is seen in an antigenic peptide having the amino acid sequence of SEQ

ID NO:2, wherein a helper T cell epitope of tetanus toxoid, residing in the sequence of amino acids 2-15 of SEQ ID NO:2, is linked to a B cell epitope of CETP, residing in the sequence of amino acids 16-31 of SEQ ID NO:2. Thus, a peptide having an amino acid sequence of SEQ ID NO:2 is an example of an antigenic vaccine peptide that has all of the qualifications for use in Applicants' invention as recited in independent Claim 28.

Conclusion and Provisional Election

Applicants submit, in view of the foregoing remarks, that the claims currently under examination are properly viewed as relating to a single *method* that uses an antigenic vaccine peptide. Such an antigenic vaccine peptide is not a single helper T cell epitope or limited to a few well known examples of helper T cell epitopes. Accordingly, Applicants respectfully urge the Examiner to reconsider and withdraw the species election for pending Claims 28, 29, and 37-39.

Applicants understand the species election requirement as seeking an election among the helper T cell epitope embodiments listed in Claim 29. Although Applicants believe that the requirement for an election of a species is improper and based on a misapprehension of the claimed invention, and without in any way acquiescing to the reasons for the requirement set forth in the Office Action, but in order to be fully responsive to the Office Action, Applicants provisionally elect tetanus toxoid from the list of several, well known examples of helper T cell epitopes in Claim 29. All pending claims read on the elected species.

Respectfully submitted,

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May 8, 2002
date of mailing and signature

Stephanie L. Leicht
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